IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
WANNEMACHER, *et al.*	Art Unit: 1644
Serial No.: 09/960,315	Examiner:
Filed: 24 September 2001	Atty. Dckt: 034047.004CON1 (RIID 99-12A)
For: DEGLYCOSYLATED RICIN TOXIN A-CHAIN VACCINE	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Mail Stop: AF

Dear Sir:

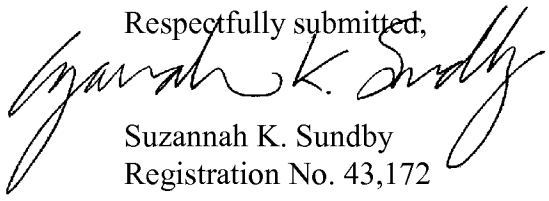
Applicants request review of the final rejection in the above-referenced application. An amendment is being filed with this request.

This Request is being filed with a Notice of Appeal.

The Review is requested for the reasons stated on the attached sheets.

I am the Attorney of Record.

Respectfully submitted,



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REASONS FOR REVIEW REQUEST

The Claimed Invention

The claimed invention is directed to a method of immunizing a subject from ricin intoxication by inhalation which comprises administering to the subject an amount of a deglycosylated ricin-A chain lacking about 50% of the mannose and most fucose residues present on the wild-type ricin toxin A-chain and having the ricin B-chain removed. Dependent claims are directed to how the deglycosylated ricin-A chain is chemically deglycosylated (claim 48), dosages and amounts administered (claims 49-51), compositions, adjuvants, and formulations (claims 52 and 55-56) and neutralizing antibodies (claim 53).

The Issue

Whether there is the requisite motivation to combine the disclosures of Thorpe et al. and Yan et al. when the teachings and objectives of Thorpe et al. are opposite to those of Yan et al.

The Law

1. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

2. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *See In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

The Facts

Thorpe et al. is directed towards killing target cells with ricin immunotoxins rather than immunizing a subject with a toxin modified to have reduced toxicity. Thorpe et al. teaches modifying ricin by removing carbohydrates in order to increase the potential toxicity of ricin and immunotoxins. Conversely, Yan et al. is directed towards immunizing a subject against ricin intoxication with a ricin toxoid rather than killing target cells with a ricin immunotoxin. Yan et

al. teaches treating ricin with formaldehyde to result in a ricin toxoid having decreased toxicity and then immunizing a subject with the toxoid.

Applicants respectfully submit that since the teachings and objectives of Thorpe et al. and Yan et al. are opposite to each other, one skilled in the art would not be motivated to combine their disclosures. In particular, a skilled artisan wanting to improve or enhance the activity of an immunotoxin would not be motivated to decrease its toxicity and a skilled artisan wanting to improve or enhance a toxoid suitable for use as a vaccine would not be motivated to increase its toxicity.

Applicants respectfully submit that since Thorpe et al. teaches increased toxicity of the deglycosylated RTA, one skilled in the art would reasonably believe that the deglycosylated RTA would be unsatisfactory for use as a toxoid (having reduced toxicity) in order to immunize a subject. In addition, Applicants submit that immunizing a subject against ricin intoxication would be unsatisfactory for the purposes of Thorpe et al. – using as an immunotoxin to kill target cells. Since the combination of Thorpe et al. and Yan et al. would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicants also respectfully submit that the combination of Thorpe et al. and Yan et al., i.e. using the deglycosylated RTA of Thorpe et al. to immunize a subject, would change the principle operation of Thorpe or Yan et al. – using the toxicity of a toxin to kill target cells with an immunotoxin vs. providing immunity against a toxin to prevent toxicity. Since the combination of Thorpe et al. and Yan et al. would change the principle of operation of either Thorpe et al. or Yan et al., then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *See In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Therefore, Applicants respectfully submit that a *prima facie* case of obviousness has not been established because (1) the combination of Thorpe et al. and Yan et al. would render the prior art being modified unsatisfactory for its intended purpose, and (2) the combination of Thorpe et al. and Yan et al. would change the principle of operation of either Thorpe et al. or Yan et al.

Therefore, Applicants respectfully request that the review panel decide Finding 2 or Finding 3. If the review panel decides Finding 2, Applicants would appreciate a proposed amendment if appropriate.